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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,793	PARANHOS-BACCALA ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/07/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-36,41-43 and 46* is/are pending in the application.

4a) Of the above claim(s) *8-15, 17-20, 22-36, and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,16,21 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 7-36, 41-43 and 46are pending.
Claims 8-15, 17-20, 22-36, and 41-43 are withdrawn.
Claims 1, 7, 16, 21, and 46 are examined on the merits.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office Action is in reply to Applicants' correspondence of 03/07/2008. .
Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put the application in condition for allowance. No new grounds of rejection are presented in this Office Action. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.
This Action is made **FINAL**.

Withdrawn Claim Objections

1. The objections to claims 2 and 3 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, are **WITHDRAWN** in light of the cancellation of claims 2 and 3.

Maintained Claim Rejections - 35 USC § 102

2. In the rejection of the pending claims, the required sequence elements of the claimed nucleic acids are considered an inherent property of human nuclear DNA and RNA from the plasma of human multiple sclerosis patients. Thus the cited references anticipate the broadly claimed nucleic acid molecules even though the cited references may not specifically disclose the nucleic acid or amino acid sequences recited in the claims. Concerning the inherent nature of the claimed sequence in human genomic DNA and RNA from the plasma of human MS patients, MPEP 2112 clearly indicates that: something which is old does not become patentable upon the discovery of a new

property; and that the inherent feature of a product need not be recognized in the prior art at the time of invention.

As such, in the rejection of claims under 35 USC 102 the USPTO has basis for believing that the claimed nucleic acid molecules are an inherent part of the nucleic acids referenced in the cited prior art. The MPEP in chapter 2100 states:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the rejection of claims, the specification does not exemplify or provide any indication that the sequence disclosed as SEQ ID NO: 2 and encoding the amino acid of SEQ ID NO: 31 is not an inherent part of the human genome. As such there is no evidence supporting any structural difference between the claimed nucleic acids and the nucleic acids of the cited prior art.

3. Claims 1, 7, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perron et al (1997).

Perron et al teaches a sample of RNA extracted from the plasma of a human MS patient (p.7584 – RNA extraction, cDNA synthesis, and PCR amplification from MS plasma samples). The RNA extracted from the plasma of a human MS patient inherently comprises a transcript that is a sequence encoding an expression product where the expression product comprises SEQ ID NO: 31.

Regarding claims 1 and 16, as detailed above, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that comprises SEQ ID NO: 31. With regard to claim 16, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Regarding claims 7 and 21, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that comprises SEQ ID NO: 31, where the RNA is a transcription product. With regard to claim 21, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Response to Remarks

Applicants have traversed the rejections of claims 1, 7, 16, and 21 under 35 USC 102 as anticipated by Perron et al. Applicants arguments (p.7-9 of Remarks) have been fully and carefully considered but are not found to be persuasive.

Applicants initially argue (p.8 and 9 of Remarks), that the rejected claims are drawn to a nucleic acid that is 'isolated', whereas the cited reference teaches nucleic acids that are 'extracted', and that one of skill in the art would recognize that simply extracting genetic material from a cell does not rise to the level of isolating a specifically-defined nucleic acid molecule or a specifically defined transcription product. Applicants argue that the nucleic acid of Perron et al is not 'isolated'. With this argument Applicants attempt to impart some specific definition for the term 'isolated', where the specification as originally filed provides no limiting definition regarding what is required for any nucleic acid to be 'isolated'. While the term 'isolated' does differentiate the claimed nucleic acids from nucleic acids comprising the same sequences as may be found in nature (e.g. within a living cell that is not manipulated by the hand of man) (Remarks p.10), the term does not differentiate the claimed nucleic acids from those extracted from a plasma sample, as taught by Perron et al. Indeed the term 'isolated' is used in the art to denote nucleic acids extracted in the same manner as those of Perron

et al, where for example, Zsigmond et al (1995) uses the term 'isolated' (p.1454 – Isolation and analysis of nucleic acids) to refer to total nucleic acids extracted from a sample by chemical methods, where the cited prior art of Perron et al uses chemical methods to obtain nucleic acids from a sample. Thus, the extracted nucleic acids of Perron et al are isolated nucleic acids.

Applicants further argue (p.9 of Remarks) that Perron et al does not enable one skilled in the art to obtain the claimed isolated nucleic acids as the reference does not disclose of the recited sequences. The examiner maintains that the disclosure of RNA extracted from MS plasma samples is a disclosure of isolated nucleic acids with the required sequence elements, and thus there is no further experimentation required to arrive at the claimed nucleic acids.

Applicants further argue (p.10 of Remarks) that in the rejection based on the inherency of the claimed sequences in the extracted samples of Perron et al has a basis in fact and/or technical reasoning that the recited sequences are inherently present in nucleic acids of the cited reference. In response to this argument the Examiner points out that the USPTO does not have laboratory facilities to assist in the analysis of the nucleic acids of the prior art. However, the nucleic acids of the cited reference are extracted from extracellular virions from MS patient cell cultures (Perron et al, p.7584), where the instant specification teaches (p.2) that the claimed nucleic acid sequences were obtained from overlapping cDNA fragments of retroviral RNA related to autoimmune disease such as multiple sclerosis. As such the USPTO has a factual

basis in asserting that the nucleic acids of the rejected claims are identical to the nucleic acids extracted from the plasma of an MS patient as taught by Perron et al.

As such, the rejection is maintained.

4. Claims 1, 16, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Seifarth et al (1998).

Seifarth et al teaches an analysis of human genomic DNA digested with either BamHI or HindIII (Fig 3). Such DNA includes a nucleic acid molecule comprising SEQ ID NO: 2 considering that SEQ ID NO: 2 is an inherent part of the human genome, and that SEQ ID NO: 2 itself does not contain either a BamHI of HindIII restriction site (as such the sequence of SEQ ID NO: 2 would remain intact in the DNA of Seifarth et al).

Regarding claims 1, 16, and 46, as detailed above, the digested human DNA of Seifarth et al inherently comprises a nucleic acid molecule comprising SEQ ID NO: 2.

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 102 as anticipated by Seifarth et al. Applicants arguments have been fully and carefully considered but are not found to be persuasive.

Applicants arguments (p.9 of Remarks) with regards to the limitation that the claimed nucleic acids are ‘isolated' have been addressed previously in this Office Action. The Examiner maintains that nucleic acids that are removed from their cellular environment and separated on a gel are 'isolated'.

With regard to Applicants arguments that the Office has not provides a basis in fact and/or technical reasoning that support the determination that the claimed nucleic acid sequences are a part of the human genome analyzed in the cited reference, the Examiner reiterates that the USPTO does not have laboratory facilities to assist in the analysis of the nucleic acids of the prior art. However, the instant specification asserts that the claimed nucleic acid sequences retroviral-related sequences that are endogenous and integrated into the human genome (p.1, lns.29-31; p.6 lns.27-30). As such the USPTO has a factual basis in asserting that the nucleic acids of the rejected claims are identical to the human genomic nucleic acids as taught by Seifarth et al.

As such, the rejection is maintained.

Requirement for Information Under 37 C.F.R. 1.105

5. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the Examiner has determined is reasonably necessary to the examination of this application.

6. The Examiner has cited Perron et al (1997) as teaching isolated nucleic acids that inherently comprises the claimed nucleic acids. It is noted that the inventors of the instant application are also authors of the Perron et al reference. The cited reference recites (p.7583, right col., lns.14-16): The entire sequence of this novel retroviral genome is currently being obtained using RT-PCR in RNA from extracellular virions. The information requested is as follows:

Was the sequence of the virion (identified in the cited reference as MSRV (previously identified as “LM7 virus")) obtained from the plasma of MS patients, and if so

did that sequence contain SEQ ID NO: 2 of the instant application. Was the sequence of a gag gene from the MSRV virion of the cited reference identified, and what was that sequence. Was any gene or transcript comprising SEQ ID NO: 2 of the instant application, or comprising a sequence that encodes SEQ ID NO: 31 of the instant application, identified in the MSRV virion genome.

7. Furthermore, it is noted that the instant application references the NIGMS somatic hybrid Mapping Panel #2 of Drwinga et al (see specification p.16 lns.10-26; and Abstract cited on the PTO-892 included with this Office Action) with regard to PCR amplification of a nucleic acid comprising SEQ ID NO: 2 of the instant application that encodes SEQ ID NO: 31 of the instant application (specification p.18 lns.34-38). The information requested is as follows:

Was a nucleic acid comprising SEQ ID NO: 2 of the instant application, or a nucleic acid comprising a sequence encoding SEQ ID NO: 31 of the instant application, identified in the Mapping Panel 2 of Drwinga et al, and if so an identification of that nucleic acid (e.g. which chromosome or solution reagent). Was a nucleic acid comprising SEQ ID NO: 2 of the instant application, or a nucleic acid comprising a sequence encoding SEQ ID NO: 31 of the instant application, amplified from isolated chromosome DNA ragent of Mapping Panel 2 of Drwinga et al, and if so which nucleic acids from Drwinga et al were used as the template in the PCR reaction.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement

under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633

Conclusion

No claim is allowable. No claim is free of the prior art.

8. No new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/
Examiner, Art Unit 1634

/Jehanne S Sitton/
Primary Examiner, Art Unit 1634